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Infectious Substances; Final Rule

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 172, 173, and 178

[Docket No. HM–181G; Amdt. Nos. 171–138, 172–146, 173–247, 178–111]

RIN 2137–AC36

Infectious Substances

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Final rule.

SUMMARY: RSPA published a notice of proposed rulemaking (NPRM) in December 1994 that proposed to revise the regulations pertaining to infectious substances, including regulated medical waste (RMW). In this final rule, RSPA is revising requirements for Division 6.2 materials (infectious substances). This rule clarifies the scope of regulation for infectious substances, provides relief for certain shipments of RMW that conform to other Federal agency regulations, allows certain quantities of RMW to be transported by aircraft, and makes other changes to clarify regulatory provisions applicable to infectious substances. This rulemaking action is necessary to ensure that the regulations for infectious substances and regulated medical waste are cost effective and provide an adequate level of safety in transportation.

DATES: *Effective date.* The effective date of these amendments is October 1, 1995.

Compliance date. Voluntary compliance with the regulations, as amended herein, is authorized immediately. The mandatory compliance date for these regulations is January 1, 1996.

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SUPPLEMENTARY INFORMATION:

I. Background

In a final rule published on September 22, 1994 (59 FR 48762), RSPA revised 49 CFR 171.14(b) to delay the compliance date for requirements applicable to RMW and materials infectious only to animals from October 1, 1994, to October 1, 1995. RSPA also delayed the compliance date for requirements for infectious substances, other than RMW and animal-only pathogens, from October 1, 1994, to January 1, 1995.

On December 21, 1994, RSPA published a notice of proposed rulemaking and announced a public meeting under Docket HM–181G (59 FR 65860). In the notice, RSPA proposed to revise the requirements for infectious substances, including regulated medical waste, which were adopted in final rules under Docket HM–181 in December 1990 and 1991. Some of the proposals contained in the NPRM were substantive, such as the proposal to add an exception from specific packaging and labeling requirements for RMW if it is prepared in accordance with the regulations of the Occupational Safety and Health Administration (OSHA). However, the majority of the changes proposed in the notice were minor and primarily intended to ease compliance by clarifying the requirements. Also in the NPRM, RSPA outlined issues for possible future rulemaking action. The public meeting, which gave interested persons an opportunity to orally present their comments on the notice, was held on January 17, 1994, in Washington, DC.

This rule was developed, with the concerns of the health care industry and medical waste companies in mind, in coordination with other Federal agencies (e.g., OSHA, Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Environmental Protection Agency (EPA)) to minimize differences between the Hazardous Materials Regulations (HMR) and other Federal agency regulations to ease compliance and eliminate gaps and inadequacies in regulatory coverage to assure that safety is maintained in transportation. RSPA will continue to be aware of significant steps being taken by other Federal agencies to remain cognizant of potential impacts regarding infectious substances and regulated medical waste prior to their entering, and in, transportation.

In March 1995, the President directed Federal agencies to review all agency regulations to eliminate or revise those that are outdated or in need of reform. RSPA issued a notice on April 4, 1995, under Docket HM–222 (60 FR 17049), that announced its review of the HMR and related programs and solicited comments on possible candidates for elimination or revision to provide clarity or relief from undue requirements. The provisions contained in this final rule contribute to meeting the goals of the President's Regulatory Reinvention Initiative.

II. Summary of Comments and Regulatory Changes

RSPA received 41 written comments on the notice of proposed rulemaking and 4 oral statements at the public meeting. The comments were submitted by hospitals, pharmaceutical companies, trade associations, packaging manufacturers, academic institutions, transporters of medical waste, and private individuals. Commenters generally supported RSPA's efforts to amend the regulations to regulating those materials that likely pose a threat in transportation to ensure the safe transportation of infectious substances and RMW. The commenters also were pleased that RSPA coordinated with other Federal agencies in the development of these regulations. Several commenters stated that, although the proposed amendments narrowed the scope of and clarified the infectious substance and RMW provisions, they need more refinement. The commenters predominantly addressed the following topics: (1) The definition of ''regulated medical waste''; (2) exclusion of discarded cultures and stocks from the definition of RMW; (3) a packaging and labeling exception for RMW; (4) a laundry exception; (5) the definitions of ''biological product'' and ''diagnostic specimen'' and retention of exceptions for these materials; and (6) aligning the infectious substance provisions with the international standards. A detailed discussion of the comments and RSPA's response to them is provided in the following summary.

A. Definition of RMW

RSPA received numerous comments concerning the proposed revision of the definition of ''regulated medical waste'' (RMW). The majority of commenters favored RSPA's proposal to limit the definition of RMW to materials containing an infectious substance. Commenters stated that RSPA defined RMW rationally, and that this definition would significantly reduce the amount of medical waste required to be specially handled without jeopardizing transportation safety. Also, commenters stated that the proposed definition, which allows shippers to segregate their waste, is more cost-effective than treating all waste as RMW. One commenter stated, ''Adoption of a criteria-based definition, as opposed to a list-based definition, also eliminates the categories of waste (e.g., unused sharps) that are not hazardous.''

Some commenters raised concerns that the proposed definition of RMW is impractical and does not account for the fact that RMW is rarely ''known to contain'' an infectious substance. Commenters claimed that, in order to confirm the presence of an infectious substance, medical waste would have to undergo cost-prohibitive testing.

Commenters stated that shippers are forced to make a ''best guess'' as to whether a medical waste is subject to the HMR, increasing the potential for undeclared shipments of RMW. In addition, commenters argued that not all personnel who are responsible for identifying and packaging the wastes possess the knowledge required to make an accurate assessment. A commenter claimed that if RMW is not clearly defined and if guidance is not provided, the volume of waste treated as RMW will increase and potentially infectious waste will go undeclared in the solid waste stream. One commenter stated that the definition ''fails to provide the appropriate guidance to the health care worker responsible for segregating the regulated medical waste stream and is virtually impossible to enforce.'' Some commenters recommended that RSPA adopt ''Universal Precautions,'' a method of infection control introduced by CDC which considers all blood and certain body fluids, whether or not known to be infectious, are treated as if known to be potentially infectious. The commenters added that universal precautions are widely used in the health care industry and, if adopted, would be consistent with current practices. Some commenters requested that RSPA add language to the definition of RMW to include those materials that ''may'' or ''are suspected to'' contain an infectious substance to eliminate some of the guesswork. While some commenters asked RSPA to expand the definition of RMW, other commenters stated that RSPA's definition should be narrowed further. One commenter asserted that the proposed definition is ''inaccurate and inconsistent with science'' and claimed that essentially all material, including human skin, harbor a population of microorganisms capable of causing infection in a susceptible host. The commenter stated, ''[T]he mere presence of an infectious substance does not result in risk of infection.'' The commenter claimed that other factors have to be present for infection to occur such as, the presence of an infectious agent in the environment, a susceptible host, a portal of entry into the host, and a sufficient dose of organisms. Some commenters requested that RSPA limit the definition of RMW to ''waste * * * which contains an infectious substance and has been causally linked scientifically to human disease acquisition.'' Another commenter added, ''RSPA's definition, if applied literally, would result in classifying as regulated medical waste virtually all of the waste that is generated in the health care environment.''

RSPA has considered the commenters' suggestions. With regard to universal precautions, RSPA acknowledges that they are widely used in the workplace as recommended in CDC guidelines and required under OSHA regulations contained in 29 CFR 1910.1030. In addition, RSPA agrees that broadening the scope of RMW to include all waste containing blood or certain body fluids may ease RMW identification when the exact constituents of a waste stream are not known. However, RSPA believes that this concept might result in overregulation if adopted for the purposes of transportation. At this time, RSPA has no evidence to support the conclusion that the benefits associated with implementing universal precautions in transportation outweigh the compliance costs and regulatory burdens imposed. Therefore, RSPA is not adopting universal precautions in this rule. RSPA agrees with commenters that the principles of disease transmission (i.e., presence of an infectious agent in the environment, susceptible host, portal of entry, sufficient virulence, and sufficient dose of organisms to cause infection) would support limiting the definition to those wastes that in fact pose a hazard in transportation. However, RSPA believes that this definition would be difficult and, in some cases, impossible to implement since certain factors, such as the dose of organisms sufficient to cause infection, are not known by most shippers. Therefore, RSPA is not adopting the principles of disease transmission for general applicability. RSPA does not agree with the commenters who requested that the definition of RMW be revised to mean ''waste * * * which contains an infectious substance and has been causally linked scientifically to human disease acquisition.'' While the commenters' suggestion supports a definition based on scientific considerations, RSPA believes that the definition is not practical for all shippers. To determine whether a particular waste has been linked to disease acquisition requires knowledge of any incidents that have occurred involving that waste. This information is not available to most shippers. Therefore, RSPA is not revising the definition as requested. However, for shippers that possess this information for a given waste stream, RSPA believes that the information may be used to determine whether the waste requires special handling as RMW.

In the proposed rule, RSPA attempted to correct an existing oversight in the HMR with regard to hazard precedence in a case involving a material that meets the definitions of both Division 6.2 and Class 7. The oversight is found in § 173.2a(c), which prescribes that a Division 6.2 material that meets the definition of another hazard class or division is required to be classed as Division 6.2. RSPA did not intend for Division 6.2 to take precedence over Class 7, other than for limited quantities of Class 7. To correct the oversight, RSPA proposed to exclude waste materials meeting the definition of Class 7 from the definition of RMW but failed to exclude Class 7 materials from the definition of an infectious substance. As proposed, Class 7 materials, including wastes, containing an infectious substance would be excepted from the RMW requirements but subject to all applicable requirements for infectious substances. In this final rule, RSPA is not adopting the wording ''other than Class 7 (Radioactive) materials'' in the proposed definition of regulated medical waste. RSPA is amending § 173.2a(c)(3) to exclude Class 7 (radioactive) materials, other than limited quantities, which also meet the definition of Division 6.2 from being classed as Division 6.2. This will alleviate the need to make changes in § 173.134 for the definitions of ''regulated medical waste'' and ''infectious substances.''

Based on the merits of comments received and RSPA's own initiative, RSPA is revising the definition of ''regulated medical waste'' as proposed. RMW is defined as ''a waste or reusable material, other than a culture or stock of an infectious substance, which contains an infectious substance and is generated in: (1) The diagnosis, treatment or immunization of human beings or animals; (2) research pertaining to the diagnosis, treatment or immunization of human beings or animals; or (3) the production or testing of biological products.'' RSPA understands that it is not always feasible for shippers to verify the presence of an infectious substance in a waste stream. The wording ''contains an infectious substance'' does not imply that the shipper is required to verify the presence of an infectious substance by testing or other means. Shippers may use information that is available to them (e.g., source of material, patient's medical history, preliminary test data) to make the most accurate determination possible as to whether or not a waste meets the definition of RMW under the HMR. If the shipper does not possess any

information concerning a waste stream, the shipper may employ universal precautions, which considers waste containing human blood and certain human body fluids as infectious. However, as previously stated, it is not RSPA's intent to require the use of universal precautions. RSPA strongly encourages the use of segregation and separation practices at the point of generation. It is our understanding that many entities currently implement such practices, which help to minimize shipping costs and ensure that only those wastes that pose a hazard are regulated.

In the NPRM, RSPA proposed to except certain categories of waste from the definition of RMW. Included was an exception for waste generated in animal husbandry or food production. RSPA received a comment requesting clarification of whether waste generated in animal research activities also would be excluded from the definition of RMW. The answer is no. Waste, generated in research activities, that contains an infectious substance and is offered for transportation or transported in commerce is regulated as RMW. The definition of RMW, as adopted in this final rule, includes waste that is generated in the diagnosis, treatment or immunization of human beings or animals or research pertaining thereto. RSPA is excluding waste generated in animal husbandry or food production because regulation of these activities under the HMR could impose burdens on agricultural and farm operations disproportionate to benefits likely to be achieved. Regulation of waste that is generated in animal research activities and contains an infectious substance is fully within the scope of the HMR.

RSPA clarified in the notice that the exceptions applicable to biological products and diagnostic specimens do not apply to materials which have become wastes. One commenter recommended that RSPA limit the definition of RMW to include only those discarded (waste) biological products and diagnostic specimens that have been confirmed to contain an infectious substance by a screening test required or recommended by the Food and Drug Administration. RSPA understands that not all biological products or diagnostic specimens are tested before shipment for treatment or disposal. Therefore, RSPA is not adopting a requirement to limit the application of the definition of RMW as requested by the commenter. If the discarded biological product or diagnostic specimen contains an infectious substance and has not been treated to eliminate the hazard, it must be shipped as RMW.

Another commenter requested that RSPA clarify that it is the responsibility of the shipper, and not the carrier, to properly class a material. The commenter stated that the waste generator is in the best position to determine whether the waste is a regulated medical waste, an infectious substance, or not regulated. In accordance with § 173.22, a person who offers a hazardous material for transportation in commerce is responsible for properly classing the material in accordance with the hazard class definitions of 49 CFR Part 173. Because this requirement already appears in the HMR, RSPA is not adding an additional requirement. Also, RSPA notes that some carriers assume responsibilities of the waste generator through contractual arrangement.

B. Discarded Cultures and Stocks

Several commenters agreed with RSPA's proposal to exclude waste cultures and stocks from the definition of RMW and subject them to requirements applicable to non-waste cultures and stocks of infectious substances. Commenters stated that cultures and stocks contain a high concentration of microorganisms that have the potential to cause disease in humans or animals and require special handling. In addition, the commenters claimed that cultures and stocks typically are treated on-site by autoclave or other treatment method. Therefore, commenters affirmed that RSPA would not be imposing an unreasonable burden on shippers by requiring the infectious substance requirements for untreated cultures and stocks. However, other commenters believed that discarded cultures and stocks should be considered as RMW. According to one commenter, most laboratories and hospitals sterilize cultures and stocks before transporting them off-site; therefore, the packaging for RMW should be adequate for the hazards posed by these materials. Another commenter asserted that waste cultures and stocks should not be treated differently from RMW but did not substantiate its claim.

In the notice, RSPA clarified that if a material has been sterilized or treated to eliminate its hazard as an infectious substance, it is not subject to the HMR, provided it does not meet the definition of any other hazard class. Therefore, cultures and stocks that have been autoclaved, incinerated, or treated by other effective means are not subject to the HMR, provided they do not meet the definition of any other hazard class. In view of the comments, RSPA is excluding untreated cultures and stocks intended for disposal from the definition of RMW. These materials are included under the definition of infectious substances.

C. RMW Packaging and Labeling Exception

In the notice, RSPA proposed to except RMW from the specific packaging requirements of § 173.197 and labeling requirements of Subpart E of Part 172 if packaged in rigid non-bulk packagings conforming to the general packaging requirements of §§ 173.24 and 173.24a and OSHA packaging and marking requirements in 29 CFR 1910.1030. RSPA proposed to limit the exception to RMW that is offered for transportation or transported by private or contract carrier. The majority of the commenters addressing this subject supported the proposed exception. Some commenters indicated that the exception will allow generators of RMW to maintain their current practices. One commenter recommended that RSPA limit the application of the RMW exception to contract carriers registered with the Federal Highway Administration (FHWA) and vehicles operated by drivers holding a Commercial Drivers License (CDL). If the exception is not modified, the commenter stated that the exception ''would be abused by any number of carriers who may not be familiar or in compliance with DOT Motor Carrier Safety Regulations or familiar with industry standards and practices.''

RSPA disagrees with this commenter. Familiarity with the Federal Motor Carrier Safety Regulations (FMCSR; 49 CFR Parts 300–399) and possession of a CDL would not necessarily enhance a carrier's or driver's specialized knowledge of medical waste requirements. In addition, the FMCSR and CDL requirements are only applicable to highway motor carriers and drivers. Because the HMR relate to all modes of transportation, the commenter's suggestion to limit the applicability of the exception to RMW transported by contract carriers registered under the FMCSR and drivers with CDLs is not adopted.

Another commenter asserted that the exception allowing OSHA packaging and marking does not sufficiently communicate the nature and risk of the package to the carrier. The commenter requested that RSPA require packages containing RMW to display the name, address, and telephone number of the generator and the date of generation. The commenter stated that in the event of a needle stick injury, OSHA requires the employer/carrier to ascertain the route of exposure. According to the

commenter, some carriers pick up RMW from several generators on a given route and it is impossible to determine the route of exposure if the source of the package is unknown.

In the NPRM, RSPA proposed to except RMW from specific packaging and labeling requirements, but not from marking or other hazard communication requirements. Section 172.301(d) requires that non-bulk packages of hazardous material be marked with the name and address of the consignee or consignor, unless the package is transported by highway and is not being transferred from one carrier to another; or is part of a carload, truckload, or freight container load, and the entire contents of the rail car, truck or freight container are shipped from one consignor to one consignee. In cases which the name and address of the consignor or consignee are not required on package markings, a carrier may, by contractual arrangement, have the waste generator mark its name and address on packages or use other means to keep track of where packages originate. RSPA does not believe there is a need for a regulatory requirement for the consignor's name and address to appear on a package in all instances. Therefore, the commenter's recommendation is not adopted.

In this final rule, RSPA is authorizing non-bulk, non-specification packagings for RMW under the conditions specified in the NPRM. RSPA intends to monitor incident reports for these shipments to ensure that the packaging and handling requirements achieve an acceptable level of safety. If they do not, RSPA will propose adjustments in future rulemaking action.

D. Exception for Laundry and Medical Equipment

To relieve the burden of compliance with both the HMR and OSHA regulations, RSPA proposed to except from the HMR contaminated laundry and medical equipment that conforms to OSHA regulations at 29 CFR 1910.1030. Of the few commenters addressing this issue, most supported RSPA's proposed exception. However, one commenter contended that laundry should not be regulated differently than RMW. The commenter reported that although OSHA requires sharps to be separated from other RMW, in reality, sharps are occasionally left in laundry which poses a hazard to personnel handling the laundry. The commenter stated, ''it is appropriate to include laundry in a RMW category because laundry, while not itself a waste, does contain RMW.''

RSPA agrees with the commenter that laundry and disposable garments share similar characteristics. However, laundry and disposable materials are handled differently from the point of generation to decontamination or disposal. Typically, laundry is segregated from waste materials at the point of generation and specially handled and reprocessed by employees dealing exclusively with laundry. Conversely, disposable garments and the like are combined with other non-sharp wastes at the point of generation and managed as medical waste, regulated or non-regulated. RSPA believes that the OSHA requirements applicable to laundry and medical equipment provide an adequate level of safety in transportation and it is unreasonable and impractical to require RMW packaging and hazard communication for laundry and medical equipment that are intended for reuse. OSHA prescribes that contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with 29 CFR 1910.1030(g)(1)(i) of the OSHA regulations or, if utilizing universal precautions, alternative labeling is permitted if it is recognizable to all employees as requiring compliance with universal precautions. In addition, OSHA requires contaminated laundry that is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container to be placed in bags or containers which prevent soak-through and/or leakage of fluids to the exterior. See 29 CFR 1910.1030(d)(4)(iv). OSHA prescribes that medical equipment, including equipment used for diagnosis, research, or treatment, shall be decontaminated, to the maximum extent practicable, before transportation. If decontamination is impractical, the equipment should be labeled with the ''BIOHAZARD'' label. See 29 CFR 1910.1030(d)(2)(xiv). In this final rule, RSPA is adopting the exception for laundry and medical equipment as proposed in the NPRM.

E. Biological Products and Diagnostic Specimens

In an attempt to clarify the scope of the HMR, RSPA proposed to amend the definitions of ''biological product'' and ''diagnostic specimen'' to include only those materials that contain an infectious substance. However, commenters' responses suggest that the proposal may have added confusion. Some commenters contended that it was illogical for RSPA to amend the definitions of biological products and diagnostic specimens to limit them to materials that contain an infectious substance, but continue to except them from the HMR. Commenters asserted that defining a ''diagnostic specimen'' as ''a material that contains an infectious substance being shipped for purposes of diagnosis'' is contradictory. One commenter argued that the primary reason a diagnostic specimen is shipped is to determine, through testing, whether or not it contains an infectious substance. Another commenter requested that RSPA keep its previous definitions of diagnostic specimen and biological product because they are consistent with other Federal regulations. RSPA agrees with the commenters and is not amending the definitions of ''biological product'' and ''diagnostic specimen'' as proposed in the notice.

Several commenters also opposed retaining the exceptions for biological products and diagnostic specimens, asserting that insufficient protection will be afforded to transport workers and the public if biological products and diagnostic specimens, especially those that are known to contain an infectious substance, are excepted from regulation. One commenter stated that these exceptions effectively eliminate Division 6.2 materials from the HMR.

RSPA agrees with commenters that some level of regulation may be needed for biological products and diagnostic specimens under the HMR to ensure safety, but RSPA is not imposing any requirements for these materials in this rule. Under the current requirements, a biological product or diagnostic specimen that contains an infectious substance is excepted from the HMR, unless the biological product or diagnostic specimen is being discarded, in which case it would be regulated as RMW. RSPA anticipates proposing to delete the exceptions for biological products and diagnostic specimens and impose appropriate requirements for these materials, if justified after evaluation of associated benefits and costs, in future rulemaking action.

F. Extension of Compliance Date

In the notice, RSPA proposed to extend the compliance date for the requirements applicable to RMW and infectious substances affecting animals only, from October 1, 1995, to January 1, 1996. Some commenters supported having additional time to come into compliance with the requirements for RMW and infectious substances affecting animals only. The commenters stated that an extension will also allow RSPA time to issue its final rule and provide regulated industry sufficient time to comply with the new changes. However, other commenters expressed concern in regard to RSPA's proposal to

extend the compliance date from October 1, 1995, to January 1, 1996. These commenters suggested that the compliance date be delayed for an indefinite period of time until the final rule has been issued and RSPA has resolved all of the issues.

RSPA disagrees with these latter comments and believes there is a need to put these requirements in place as quickly as practicable, to help eliminate ongoing confusion over what regulatory requirements apply. Also, RSPA believes that implementation on January 1, 1996 is a reasonable extension of time. Therefore, the proposal is adopted.

Because these amendments extend the compliance date from October 1, 1995, to January 1, 1996, they are effective without the customary 30–day delay following publication. This will allow the changes to appear in the next revision of 49 CFR.

G. Air Transportation

RSPA received several comments concerning the proposal to add Special Provisions ''A13'' and ''A14'' to allow certain quantities of regulated medical waste aboard aircraft. Most of the commenters supported removal of the prohibition to transport RMW by air. Some commenters questioned RSPA's rationale for the quantities selected in the proposed rule. One commenter expressed concern about allowing 12 liters of RMW by air without prescribing higher integrity packaging requirements. Some commenters stated that RMW should not be restricted to any quantity limits since the International Civil Aviation Organization (ICAO) Technical Instructions do not impose quantity limits for RMW.

RSPA selected the proposed quantity limits in the NPRM based on comments received on the March 3, 1993 advance notice of proposed rulemaking and for consistency with quantity limits under U.S. Postal Service regulations. Therefore, RSPA is adding these special provisions, as proposed, to facilitate air transportation of RMW.

H. Animal Pathogens

In the NPRM, RSPA requested comments concerning HMR regulation of infectious substances affecting animals only. RSPA received limited comments on this issue. One commenter stated that RSPA does not have the authority to regulate infectious substances affecting animals only and that the likelihood of an incident involving an animal exposed to an infectious substance as a result of a release in transportation is small.

RSPA agrees with the commenter that the probability of an incident occurring involving animals exposed to animal pathogens during transportation might be low. However, the potential exists and RSPA is aware of at least one such incident. Under the Federal hazardous material transportation law, RSPA is required to promulgate regulations for the transport of materials that may pose an unreasonable risk to health, safety and property. Protection of animals is encompassed within this jurisdiction. In addition, RSPA has determined that the costs incurred by regulation of these materials is minimal compared to the benefits acquired. In regard to other applicable Federal regulations, RSPA has examined the Department of Agriculture's regulations concerning animal pathogens contained in 9 CFR parts 1–199 and determined that they do not adequately address transportation concerns with regard to communication of hazard, provision of emergency response information, and packaging. Therefore, RSPA is regulating infectious substances affecting animals only, as proposed.

I. Other Issues

Two commenters asked RSPA to clarify its preemption authority in the preamble. The commenters suggested that States may impose requirements on the transportation of medical waste that go beyond those imposed by this rule. In particular, the commenters noted, States may define infectious substances and medical waste more broadly, to include categories of materials not regulated under the HMR. One commenter stated: ''a decision by RSPA *not* to regulate (e.g., a decision to exclude certain materials from the definition of regulated medical waste), should carry as much preemptive effect as a decision to regulate.''

As provided in Subpart C to Part 107, any law, regulation, order, ruling, provision or other requirement of a State, political subdivision, or Indian tribe that concerns a ''covered subject,'' as defined at § 107.202(a), and that is not substantively the same as any provision of the Federal hazmat law or any regulation issued thereunder, is preempted. Covered subjects include classification of, and specification of packaging and hazard communication requirements for the transportation of, hazardous materials. Non-Federal requirements pertaining to the transportation of infectious substances that concern a covered subject accordingly are subject to preemption under this standard.

The HMR do not, however, preempt non-Federal requirements imposed on the transportation of materials that are not hazardous materials as defined in the HMR. One exception to this general principle, however, would be where a non-Federal law or regulation requires a method of hazard communication for non-hazardous materials sufficiently similar to that prescribed by the HMR for a hazardous material that the regulation is ''tantamount to the creation of an additional class of hazardous materials with its own marking requirements.'' 59 FR 6186, 6192 (Feb. 9, 1994) (preemption determination PD–6). Short of this type of circumstance (*de facto* classification of materials as hazardous materials), however, State, local and tribal regulation of materials that are not hazardous materials is not subject to preemption by the Federal hazmat law. RSPA has proposed to extend application of the HMR to all intrastate transportation in a notice of proposed rulemaking published on July 9, 1993, under Docket HM–200 (58 FR 36920). Further action under that docket is pending.

RSPA received comments requesting that RSPA require treated medical waste to be physically altered until it is unrecognizable so that it can be readily identified as non-regulated. Although this practice may be required under certain State medical waste regulatory programs, RSPA is not adopting it at this time because it is beyond the scope of this rule.

In the NPRM, RSPA invited comments on possible adoption of a vehicle placarding requirement for Division 6.2 materials based on a petition for reconsideration (P–1080). Due to inadequate information, RSPA did not propose to adopt such a requirement in the NPRM but stated that it is under consideration for future rulemaking. Several commenters urged RSPA to clarify that RMW is not and will not be subject to placarding requirements. The commenters asserted that bloodmobiles carrying bulk blood intended for disposal would be subject to CDL and drug and alcohol regulations if placarding is required. RSPA is not adopting a placarding requirement, as requested by the petitioner, or vehicle marking requirement for Division 6.2 materials in this rule. However, RSPA is aware that several States have differing marking requirements for medical wastes. It may be appropriate, for purposes of national uniformity and minimum communication, to propose in future rulemaking a special marking, other than a placard, to identify the presence of these materials in a vehicle.

In the preamble of the notice, RSPA stated that this rulemaking action was limited to amendments that could be accomplished in the short term and that

more substantive issues would be addressed in future rulemaking. Some commenters contended that dividing the problematic issues into two or more rulemakings would be confusing. These commenters urged RSPA to make all necessary adjustments to the regulations in one rule.

RSPA believes that certain changes to the requirements for RMW adopted under Docket HM–181 on December 20, 1991, are necessary, before they become mandatory, to eliminate confusion and facilitate transportation of RMW. However, in order to make the necessary changes to the RMW requirements and publish the rule before October 1, 1995, RSPA had to limit the amendments in this rule to minor, short-term adjustments.

RSPA received comments requesting that bulk packaging standards for RMW be incorporated into the HMR. Currently, their use is authorized under the provisions of a number of exemptions. RSPA stated in the preamble of the notice that it anticipates proposing to convert the provisions of some or all of these exemptions into regulations of general applicability. RSPA intends to address bulk packagings for RMW in a future rulemaking.

Several commenters encouraged RSPA to align the classification, hazard communication, and packaging requirements for Division 6.2 materials in the HMR with the most recent edition of the UN Recommendations and ICAO Technical Instructions. Specifically, some commenters recommended that RSPA require infectious substances packagings to be UN marked and certified for consistency with international standards.

RSPA believes that uniform standards, applicable to both domestic and international transportation, are essential to ensuring the safe and efficient movement of infectious substances. To this end, RSPA continues to work with other Federal agencies and the United Nations Subcommittee of Experts on the Transport of Dangerous Goods to improve standards for classification, hazard communication, packaging and operational control of infectious substances. The HMR generally are consistent with the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations), although there are differences. RSPA anticipates proposing changes to the HMR in future rulemaking concerning defining criteria, particularly the adoption of risk groups and regulation of genetically-modified organisms and microorganisms, biological products and diagnostic specimens, and new shipping descriptions and marking requirements for non-bulk packagings based on the UN Recommendations. Both through rulemaking action and in working with other Federal agencies, RSPA anticipates advocating standards based on UN Recommendations.

RSPA intends to continue its review of the HMR and the regulations of other Federal agencies and to work with these agencies to identify and eliminate inconsistencies, overlaps, gaps and inadequacies in regulatory coverage. Moreover, as new information becomes available, RSPA may propose to make adjustments to the requirements for Division 6.2 materials in future rulemaking as necessary.

III. Section-by-Section

Part 171

Section 171.14. RSPA is amending § 171.14(b)(7) to change the compliance date from October 1, 1995, to January 1, 1996, to give industry additional time to comply with the changes adopted in this final rule.

Part 172

Section 172.101. RSPA is amending Column (8A) of the Hazardous Materials Table for the entries, ''Infectious substances, affecting humans'', ''Infectious substances, affecting animals'' and ''Regulated medical waste'', to reflect the correct section references. RSPA is revising the identification number in Column 4 for ''Regulated medical waste'' from ''NA9275'' to ''UN3291.'' RSPA also is adding two special provisions, ''A13'' and ''A14,'' in Column 7 for ''Regulated medical waste.''

Section 172.102. RSPA is adding Special Provisions ''A13'' and ''A14'' to permit transportation of RMW by aircraft as proposed. Special Provision A13 allows the transportation of sharps aboard passenger and cargo-carrying aircraft in quantities not exceeding 16 kilograms (35 pounds) per package and maximum liquid content of 50 milliliters (1.7 ounces) for each inner packaging. Special Provision A14 permits the transportation of RMW by aircraft in quantities of not more than 16 kilograms (35 pounds) for solid waste and 12 liters (3 gallons) for liquid waste, when means of transportation other than air are impracticable or unavailable. These provisions are necessary to facilitate transportation of RMW in rural areas and ensure that shippers of used sharps do not encounter unnecessary delays or frustration of shipments.

Part 173

Section 173.2a. RSPA is amending § 173.2a(c)(3) to provide that Division 6.2 materials do not include those meeting the criteria for Class 7 (radioactive) materials, other than limited quantities. RSPA did not intend for Division 6.2 to take precedence over Class 7 materials.

Section 173.134. RSPA is revising § 173.134 for clarity and to provide relief from overly restrictive requirements for certain shipments of RMW. RSPA is not amending the definitions of ''biological product'' and ''diagnostic specimen'' as proposed. RSPA believes, based on commenters' observations, that clarifying RSPA's intent in the preamble is likely to be more effective than revising the definitions.

Based on comments received, RSPA is relocating the definition of ''regulated medical waste'' and its exceptions from Appendix G of Part 173 to § 173.134 to ease compliance with the HMR. In addition, RSPA is relocating the exceptions for biological products and diagnostic specimens from § 173.196 to § 173.134. RSPA is adding an exception for material that once contained an infectious substance but has been treated to eliminate the hazard. In addition, RSPA is clarifying that the following materials are not considered RMW: (1) EPA hazardous wastes; (2) waste derived from households; (3) corpses, remains, and anatomical parts intended for ceremonial interment or cremation, and (4) animal waste generated in animal husbandry or food production.

Based on commenters' requests and RSPA initiative, RSPA is revising the definition of RMW by adopting a criteria-based definition as opposed to a list-based definition, that is, removing the categories in Appendix G and replacing them with a general definition. Regulated medical waste is defined as a waste or reusable material, other than a culture or stock of an infectious substance, that contains an infectious substance and is generated in the diagnosis, treatment or immunization of human beings or animals, research pertaining thereto, or the production or testing of biological products.

Also in § 173.134, RSPA is adding an exception for RMW that is packaged in a rigid, non-bulk packaging that meets the general packaging requirements of §§ 173.24 and 173.24a, meets packaging and marking requirements in 29 CFR 1910.1030, and is offered for transportation or transported by private or contract carrier.

In paragraph (c) of this section, RSPA is clarifying that Division 6.2 materials other than RMW are not assigned a packing group. RMW is assigned to a Packing Group II performance level.

Part 178

Section 178.609. RSPA is adding a new paragraph (i) to clarify that packagings for infectious substances conforming to this section are not required to be marked and certified in accordance with § 178.503.

IV. Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule is considered a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, was reviewed by the Office of Management and Budget. This rule is significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034), because of substantial public interest. A regulatory evaluation is available for review in the docket.

B. Executive Order 12612

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 (''Federalism''). Federal law expressly preempts State, local, and Indian tribe requirements applicable to the transportation of hazardous material that cover certain subjects and are not substantively the same as the Federal requirements. 49 U.S.C. 5125(b)(1). These subjects are:

(A) the designation, description, and classification of hazardous material;

(B) the packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(C) the preparation, execution, and use of shipping documents pertaining to hazardous material and requirements respecting the number, content, and placement of those documents;

(D) the written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or

(E) the design, manufacturing, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container which is represented, marked, certified, or sold as qualified for use in the transportation of hazardous material.

This final rule concerns the classification, packaging, labeling, and handling of hazardous material, among other covered subjects.

This rule preempts any State, local, or Indian tribe requirements concerning these subjects unless the non-Federal requirements are ''substantively the same'' (see 49 CFR 107.202(d)) as the Federal requirements.

Federal law (49 U.S.C. 5125(b)(2)) provides that if DOT issues a regulation concerning any of the covered subjects after November 16, 1990, DOT must determine and publish in the Federal Register the effective date of Federal preemption. That effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. The effective date of Federal preemption for the requirements in this final rule that concern covered subjects is January 1, 1996.

C. Regulatory Flexibility Act

This final rule revises requirements for infectious substances and regulated medical waste contained in the HMR by narrowing the scope of these provisions. The changes in this rule provide relief to shippers, carriers of infectious substances and regulated medical waste, and some packaging manufacturers. Although the changes will affect many small entities, such as medical clinics, we expect the economic impact on each of them to be minimal. Therefore, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

There are no new information collection requirements in this final rule.

E. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN numbers contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR Part 172

Hazardous materials transportation, Hazardous waste, Labeling, Marking, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR Part 178

Hazardous materials transportation, Motor vehicle safety, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, 49 CFR parts 171, 172, 173, and 178 are amended as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

2. In § 171.8, the following definition is added in appropriate alphabetical order to read as follows:

§ 171.8 Definitions and abbreviations.

* * * * *

Regulated medical waste. See § 173.134 of this subchapter.

* * * * *

§ 171.14 [Amended]

3. In § 171.14, as revised at 59 FR 67406, effective October 1, 1995, in paragraph (a)(1)(ii), in the heading, the wording ''*October 1, 1995*'' is revised to read ''*January 1, 1996*'' and, in the regulatory text, the wording ''October 1, 1995'' is revised to read ''January 1, 1996''.

§ 171.15 [Amended]

4. In § 171.15, the wording ''etiologic agents'' in paragraphs (a)(3) and (b) introductory text is revised to read ''infectious substances (etiologic agents)''.

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

5. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

§ 172.101 [Amended]

6. In § 172.101, in the Hazardous Materials Table, as revised at 59 FR 67409, effective October 1, 1995, the following changes are made:

a. For the entry, ''Infectious substances, affecting animals *only*'', in Column (8A), ''196'' is removed and replaced with ''134''.

b. For the entry, ''Infectious substances, affecting humans'', in Column (8A), ''196'' is removed and replaced with ''134''.

c. For the entry, ''Regulated medical waste'', in Column (4), the identification number ''NA9275'' is removed and replaced with ''UN3291''; in Column (7), ''A13, A14'' is added; and in Column (8A), ''197'' is removed and replaced with ''134''.

7. In § 172.102, in paragraph (c)(2), Special Provisions A13 and A14 are added in alphanumeric sequence, to read as follows:

§ 172.102 Special provisions.

* * * * *

(c) * * *

(2) * * *

Code/Special Provisions

* * * * *

A13 Non-bulk packagings conforming to § 173.197 of this subchapter not exceeding 16 kilograms (35 pounds) gross mass containing only used sharps are permitted for transportation by aircraft. Maximum liquid content in each inner packaging may not exceed 50 milliliters (1.7 ounces).

A14 Non-bulk packagings of regulated medical waste conforming to § 173.197 of this subchapter not exceeding 16 kilograms (35 pounds) gross mass for solid waste or 12 liters (3 gallons) total volume for liquid waste may be transported by passenger and cargo aircraft when means of transportation other than air are impracticable or not available.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

8. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

9. In § 173.2a, paragraph (c)(3) is revised to read as follows:

§ 173.2a Classification of a material having more than one hazard.

* * * * *

(c) * * *

(3) A Division 6.2 (infectious substance) material that also meets the definition of another hazard class or division, other than Class 7, or that also is a limited quantity Class 7 material, shall be classed as Division 6.2;

* * * * *

10. Section 173.134 is revised to read as follows:

§ 173.134 Class 6, Division 6.2—Definitions, exceptions and packing group assignments.

(a) *Definitions.* For the purposes of this subchapter, the categories of materials that constitute Division 6.2 are defined as follows:

(1) An *infectious substance* means a viable microorganism, or its toxin, that causes or may cause disease in humans or animals, and includes those agents listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Services and any other agent that causes or may cause severe, disabling or fatal disease. The terms *infectious substance* and *etiologic agent* are synonymous.

(2) A *diagnostic specimen* means any human or animal material including, but not limited to, excreta, secreta, blood, blood components, tissue, and tissue fluids, being shipped for purposes of diagnosis.

(3) A *biological product* means a material that is prepared and manufactured in accordance with the provisions of 9 CFR part 102 (Licenses for biological products), 9 CFR part 103 (Experimental products, distribution, and evaluation of biological products prior to licensing), 9 CFR part 104 (Permits for biological products), 21 CFR part 312 (Investigational new drug application), or 21 CFR parts 600 to 680 (Biologics).

(4) A *regulated medical waste* means a waste or reusable material, other than a culture or stock of an infectious substance, that contains an infectious substance and is generated in—

(i) The diagnosis, treatment or immunization of human beings or animals;

(ii) Research pertaining to the diagnosis, treatment or immunization of human beings or animals; or

(iii) The production or testing of biological products.

(b) *Exceptions.* (1) The following are not subject to any requirements of this subchapter if the items as packaged do not contain any material otherwise subject to the requirements of this subchapter:

(i) Biological products;

(ii) Diagnostic specimens;

(iii) Laundry or medical equipment that conforms to 29 CFR 1910.1030 of the regulations of the Occupational Safety and Health Administration of the Department of Labor;

(iv) A material, including waste, that previously contained an infectious substance and has been treated by steam sterilization, chemical disinfection, or other appropriate method, so that it no longer poses the hazard of an infectious substance;

(v) Any waste material, including garbage, trash and sanitary waste in septic tanks, derived from households, including but not limited to single and multiple residences, hotels and motels;

(vi) Corpses, remains and anatomical parts that are intended for ceremonial interment or cremation; and

(vii) Animal waste generated in animal husbandry or food production.

(2) A hazardous waste is not subject to regulation as a regulated medical waste.

(3) A regulated medical waste that is transported by a private or contract carrier is excepted from—

(i) The requirement of an ''INFECTIOUS SUBSTANCE'' label if the outer packaging is marked with a ''BIOHAZARD'' marking in accordance with 29 CFR 1910.1030; and

(ii) The specific packaging requirements of § 173.197, if packaged in a rigid non-bulk packaging conforming to—

(A) The general packaging requirements of §§ 173.24 and 173.24a; and

(B) Packaging requirements specified in 29 CFR 1910.1030.

(c) *Assignment of packing groups and applicable packaging sections.* (1) Division 6.2 materials, other than regulated medical waste, are not assigned a packing group. Packaging requirements for these materials are prescribed in § 173.196.

(2) Except as otherwise provided, regulated medical waste is assigned to Packing Group II and must be packaged as specified in § 173.197.

Appendix G [Removed]

11. Appendix G to part 173 is removed.

PART 178—SPECIFICATIONS FOR PACKAGINGS

12. The authority citation for part 178 continues to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

13. In § 178.609, paragraph (i) is added to read as follows:

§ 178.609 Test requirements for packagings for infectious substances (etiologic agents).

* * * * *

(i) Packagings subject to this section are not subject to § 178.503 or any other requirements of this subpart, except § 178.608.

Issued in Washington, DC on September 14, 1995, under authority delegated in 49 CFR part 1.

D.K. Sharma,

Administrator, Research and Special Programs Administration.

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